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(54) Title: CONTAINERS FOR MEDICAL FLUIDS

(57) Abstract

Disclosed are containers of polymer materials for medical fluids assembled of a bottle formed container body (1, 10) and a closure device (4, 11), which fulfil the requirements of being capable to withstand heat sterilizing procedures and yet be made from parts which can be collected for recycling in a single process. The inventive containers will also be sealed during the sterilizing by weak seal weldings.

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Containers for medical fluids

Field of invention

The present invention relates to improved thermoplastic containers for medical fluids which are terminally sealed when autoclaving the filled containers.

Background of the invention

When developing containers for medical fluids a number of aspects must be considered. The medical fluids must retain their integrity to the highest possible extent during long term storage in different environments. A condition to be set on the containers is therefore that they shall maintain their protecting properties after autoclaving procedures. The material traditionally used in pharmaceutical industry is glass, although it is expensive and in many ways difficult to handle, it is still regarded as optimal, due its excellent capacity to withstand autoclavation without any form of degradation.

Polymeric materials are cheap and convenient to use, but they often deteriorate in their capacity of providing an oxygen and a water barrier after autoclaving. Another drawback with polymeric materials is that they can be incompatible with sensitive medical fluids intended for parenteral administration. There are several examples of how plasticizers and other components with deleterious effects have dissolved into medical fluids during storage. Many medical materials are prepared from halogenated hydrocarbons like PVC and PVDC, which have excellent properties after heat sterlization. These materials will, however, today be avoided for the long term storage of fluids because of the mentioned dissolvement problems and also because of their negative influence on the environment. Another problem with polymeric materials, especially those found in conventional bottle-type medical containers, is related to the sealing of the filled containers and the subsequent sterilizing of the goods before storage. The quality of the sealing devices will frequently be so deteriorated after heat sterilisation, such as autoclaving, that leakages appear. Rubber devices, i.e. linings, have traditionally been used to provide flexible sealings, which are capable to maintain sealing properties after autoclaving.

There is, a rising demand for medical containers and containers for consumer goods that can be recycled in a single process. This condition will presumably be set on many containers by national authorities when a new product is introduced. Conventional plastic containers for medical fluids often consist of a bottle-shaped container body, a cap and an elastomer sealing device, each made from different polymer materials, which can not be recycled together by melting and further mechanical treatment in the same process. It results in containers that are disposed as conventional garbage after use, rather than being returned to the manufacturer for recycling.

The U.S. patent 4,606,470 discloses a container having the container body, the neck and the cap all made of the same plastic, material such as polyethylene or polypropene which is potentially possible to recycle. This container is sealed by a spin fusion technique, whereby the closure is rotated relative the container and the resultant friction heat leads to sealing fusion by partial melting.

The U.S. patent 4,640,427 teaches how to seal a thermoplastic container by means of applying radiant energy from a laser to partially melt and fuse a tab with the container wall.

The U.S. patent 4,011,961 describes an autoclavable plastic bottle having a cap in two parts as a closure, wherein both the cap and the bottle can be made of polypropylene. The cap is sealed to the bottle by ultrasonic welding of meltable material rings. The cap is also constructed by three different elements, an inner and an outer cap and a elastic disc which has a reclosing effect after being penetrated with a cannula.

The U.S. patent 5,033,252 is directed to autoclaving of filled polypropylene bottles with polypropylene caps. To eliminate deformation of the cap during the autoclaving, a silicon gasket is positioned between the cap and the bottle having capacity of absorbing the pressures developed by the expansion of the cap and/or the bottle.

Most of the mentioned plastic containers will be dependent on sealing methods that employs external energy sources to partially melt container details, which is resource consuming and often result in weldings that may be weakened or wasted subsequent to their autoclavation. Another drawback with the sealings obtained by melting of polymeric materials is that they normally do not have the capacity to reseal the container once the welding has been ruptured. The autoclavable constructions cited above have closing devices comprised of several parts and will be unnecessarily complicated and thereby expensive to manufacture, as well as they introduce components such an elastic

disc and a silicon gasket, that must be collected separately, if the containers shall be recycled after use.

It is the intention of the present invention to provide containers for medical fluids that can be sealed with a minimum of resource consuming processes. It is also the intention to provide containers that are easily resealable after each fluid collection by the user, in order to enable the storage of multiple dosages of the fluids for repeated administration, and thereby fulfil a requirement set by many medical authorities on e.g. containers for storing several dosages of rinsing fluids, such as fluids based on sodium chloride solutions.

Another important object of the present invention to provide containers which fulfil the requirements of being capable to withstand heat sterilizing procedures and yet be made from parts which can be recyclable together in a single process and thereby form a convenient, cheap and resource saving alternative to the conventional technology.

Description of the invention

The present invention relates to an autoclavable container for storage of medical fluids, suitable for repeated collection fluid dosages, having a bottle formed container body with an opening for receiving and/or collecting the fluids, which is closed with a closure device consisting of a cap and a flexible sealing device, wherein all parts of container consist of essentially the same polyolefin, in order to make it recyclable in the same process. An important feature of the invention is that the said sealing device, besides the polyolefin, also contains an elastomer so a weak seal is formed between the container body and/or the cap and the sealing device when autoclaving the said container.

The invention is also related to a method for sealing the said containers after they have been filled and closed, by subjecting them to autoclavation, whereby a weak seal is formed between the container body and/or the cap and the sealing device.

The sealing will take place between the connecting parts of the container and/or the cap and the sealing device during the autoclaving procedure. Since both the container body and the sealing device are made from polymers compatible with each other, the molecules in their contact surfaces will mix by inter-diffusion under the influence of the heat so a weak seal welding is formed between the said container parts, which effectively separates the medical fluid from the environment. To successfully obtain the weak seals, it is important that the sealing device contains a certain amount of elastomer, such as

dispersed EPDM-rubber, so the sealing device can exert a balancing pressure when the polyolefin container expands and contracts during the autoclaving process.

The sealing device can be pre-formed separately from the cap and assembled with the cap and the container body after the filling procedure. Alternatively, the sealing device can be formed by injection moulding directly in the cap or the sealing device can be coextruded with the cap in the same tool. Another manufacturing alternative is to spray or blow mould the bottle formed container on a pre-formed cap. The sealing device is preferably annular or disc-formed, but other forms can be possible to fit a desired form of the container and the cap.

It is also of importance for retaining the integrity of the fluid for repeated use that the sealing device both can reseal the container properly once the weak seal has been broken and that it is so resilient that it will be resealed after being pierced by a conventional injection needle used to collect a dosage of the fluids.

Detailed description of the invention

Figure 1 shows a the bottle formed container body according to a first embodiment of the invention.
Figure 2 shows a closure device according to a first embodiment of the invention.
Figure 3A shows a container according to second embodiment of the invention.
Figure 3B is a top view of the container shown in Figure 3A.

According to a first embodiment of the invention, shown in Figures 1 and 2, the container body is formed as a conventional bottle (1) with a neck part (2) and a threaded top part (3) which is engaged with a corresponding closure device, see Figure 2, consisting of a threaded cap (4) and a flexible sealing device in the form of a resilient lining (5). A suitable material for the container body (1), which is formed by blow moulding, is polypropylene of the grade PD-9122 random copolymer resin supplied by Exxon Chemical Company. The resilient lining (5) is preferably made of a polypropylene containing a compatible thermoplastic elastomer. A suitable material for the lining is Santoprene® 55 shore from Monsanto Company that besides polypropylene contains dispersed EPDM-rubber. The lining is preferably formed by injection moulding. The cap is preferably manufactured from the polypropylene Appryl 3050 MN. When autoclaving the filled and assembled container, a weak seal will be formed in the contact surface between the lining and the top part of the

container body and between the cap and the container body. The weak seal can easily be ruptured by the user by twisting the threaded cap in a conventional manner.

In a second embodiment of the inventive container shown i Figures 3A and 3B, the closure device is a cap (11) sealingly secured around the annular flange (13) of a resilient, pierceable stopper (12). The cap consists of a handle (14) attached to a knob (15). When opening the container, the handle will be turned so the knob is released from a preformed weakened or rupturable section to form an aperture in the cap (not shown), through which aperture the needle of a syringe can pierce the stopper and contact the liquid stored in the container. The bottle formed container body (10) and the cap (11) are preferably made in a single piece of material, such as polypropylene of the type PP 23M2 (random copolymer-medical grade) from Rexene® Resins, and the resilient stopper is preferably made of the above mentioned Santoprene® 55 shore from Monsanto Company. The container is manufactured by a conventional blow-fill-seal method, whereby a parison of polypropylene is formed in a suitable tool with an extruder. The parison is sealed in the bottom, and thereafter the medical fluid is filled in the formed bottle or container body, which is sealed with the resilient stopper, whereafter the cap is sealed around, and on the top of the stopper. The cap and bottle are preferably parts of the same comparison and are processed with conventional tools. After autoclaving, these parts will form a weak seal together with the resilient stopper, in the same manner, as described with the first embodiment of the invention.

The inventive containers will be used to contain medical fluids, which are subjected to autoclaving when filled in the closed container. The containers are also suitable to contain multiple dosages of the fluid for repeated use since the sealing device is capable of resealing the container after each fluid collection.

Typical medical fluids to be filled in the containers are rinsing liquids of dissolved sodium chloride, but any fluids for parenteral administration are conceivable to fill and store in the containers.

The containers according to the invention can withstand autoclaving procedures without any material deterioration effects and will be suitable for long term storage for sensitive medical fluids which must retain their integrity after repeated fluid collection.

The inventive containers can be collected for recycling after use without disassembling its parts and without any other separation processes. The collected material can be chopped to pieces, washed and dried and thereafter melted and re-granulated for new applications or moulded into new containers.

The recycling scheme for the inventive containers will be advantageously simple and free from environmental influences, since the containers during their manufacture, assembly, storage and use not have been involved in any procedures such as treatment with ultra-violet light, heat or oils. Furthermore, the containers will provide for a simple collection procedure at hospitals without any inconvenient sorting of materials or any other laborious procedures.

Claims

1. An autoclavable container for storage of medical fluids, suitable for repeated collection of the said fluid, having a bottle formed container body (1,10) with an opening for receiving the fluids which is closed with a closure device (4,11) that consists of a cap and a flexible sealing device (5,13), wherein all said parts of the container essentially consist of the same polyolefin to make it recyclable in the same process characterized in that the said sealing device also contains an elastomer so a weak seal is formed between the container body and/or the cap and the sealing device, when autoclaving the said container.

2. A container according to claim 1 characterized in that the closure device consists of a threaded bottle cap (4) and a resilient lining (5) inserted in the cap.

3. A container according to claim 1 characterized in that the closure device is a cap (11) sealingly secured around an annular flange (13) of the sealing device which is a resilient, pierceable stopper (12).

4. A container according to claims 1-3 characterized in that the polyolefin is polypropylene.

5. A container according to claims 1-3 characterized in that the polyolefin is polyethen.

6. A method for sealing a container for storage of medical fluids having a bottle formed container body (1,10) with an opening for receiving the fluids which is closed with a closure device (4,11) consisting of a cap and a flexible sealing device (5,13) characterized by filling the container body with the said fluid, closing the container body with the closure device, which parts both essentially consist of the same polyolefin and autoclaving the closed and filled container, so a weak seal is formed between the container body and/or the cap and the sealing device.

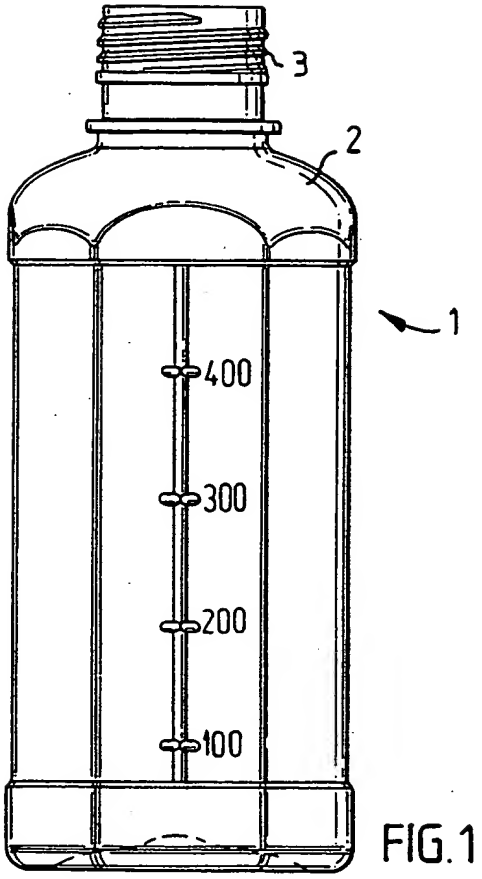

FIG.1

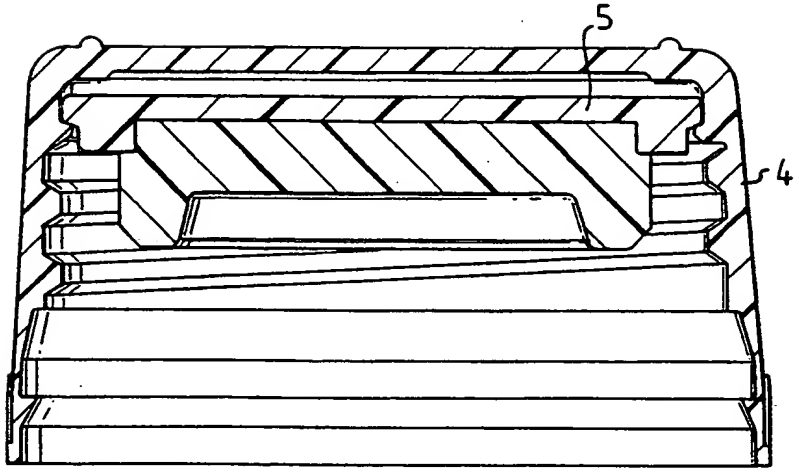

FIG.2

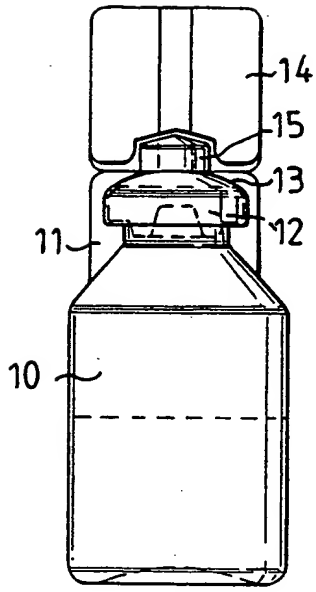

FIG. 3A

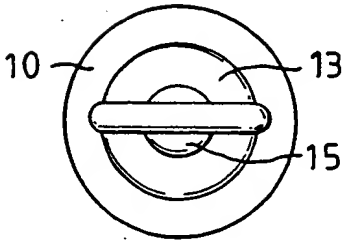

FIG. 3B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 94/00876

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61J 1/00, B65D 53/00 // B65B 55/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61J, B65B, B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB, A, 2223008 (REED PACKAGING LIMITED), 28 March 1990 (28.03.90) --	
A	WO, A1, 8912584 (M.K. PLASTICS PTY LIMITED ET AL), 28 December 1989 (28.12.89) --	
A	DE, A, 1532416 (W.R. GRACE & CO.), 27 July 1972 (27.07.72) --	
A	GB, A, 2162158 (DONALD PAUL PILLA), 29 January 1986 (29.01.86) --	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 December 1994	10 -01- 1995
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Magnus Thorén Telephone No. +46 8 782 25 00

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International application No.
PCT/SE 94/00876

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4606470 (BARLICS), 19 August 1986 (19.08.86) --	
A	US, A, 4991731 (OSIP ET AL), 12 February 1991 (12.02.91) --	
A	US, A, 5033252 (CARTER), 23 July 1991 (23.07.91) --	
A	Patent Abstracts of Japan, Vol 13,No 289, M-845, abstract of JP, A, 1-84860 (SHOWA DENKO K.K.), 30 March 1989 (30.03.89) --	

INTERNATIONAL SEARCH REPORT

Information on patent family members

26/11/94

International application No.
PCT/SE 94/00876

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A- 2223008	28/03/90	FR-A- 2659599	20/09/91
WO-A1- 8912584	28/12/89	AU-B- 627746	03/09/92
		AU-A- 3773789	12/01/90
		EP-A,B- 0481981	29/04/92
		AT-T- 110674	15/09/94
		CA-A- 1322187	14/09/93
		DE-D- 68917938	00/00/00
		FI-B,C- 91955	31/05/94
DE-A- 1532416	27/07/72	BE-A- 686948	15/03/67
		FR-E- 90994	00/00/00
		GB-A- 1152465	21/05/69
		NL-A- 6613070	16/03/67
		US-A- 3493453	03/02/70
GB-A- 2162158	29/01/86	NONE	
US-A- 4606470	19/08/86	NONE	
US-A- 4991731	12/02/91	CA-A- 2022341	04/02/91
		DE-D,T- 69008961	03/11/94
		EP-A,B- 0411385	06/02/91
		ES-T- 2056311	01/10/94
		JP-A- 3148453	25/06/91
US-A- 5033252	23/07/91	CA-A- 1317571	11/05/93
		DE-A- 3878671	01/04/93
		EP-A,B- 0322134	28/06/89
		JP-A- 1288265	20/11/89
		US-A- 4805377	21/02/89
		US-A- 4947620	14/08/90
		US-A- 4962856	16/10/90
		US-A- 5052558	01/10/91